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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,372	12/21/2001	Roger A. Sabbadini	LPT-3001-UT	3592

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EXAMINER
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GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/029,372	SABBADINI, ROGER A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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The RCE request received 9/21/07 has been entered and claims 29-42 are currently pending in this application. In the amendment to the specification, it is required to state how the prior applications are related to the present application such as continuations, divisionals. All previous rejections are hereby withdrawn in view of the submission of all new claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 29-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,881,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to treating an acute myocardial ischemic event whereas the claims of '546 are directed to treating cardiovascular disease in general by the same method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Gamble and Tabas in view of Applicant's admissions in the specification in further view of Friedrichs.

Gamble (6,649,362) entitled "Screening Method for an Agent Having an Effect on a Sphingosine Kinase Signaling Pathway" teaches in column 5 last paragraph bridging to column 6, modulating activity of sphingosine kinase pathway can be by competition with substrates such as sphingosine or ATP, interference with the catalytic activity of sphingosine kinase or interfering with enzyme activation. In column 6 lines 29-36, the pathway includes ceramide, Sph-1-P, protein kinase C. In column 7 lines 27-34, modulation is performed by administering an agent to a mammal the modulates

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synthesis of components, functions as an antagonist or agonist to components of the pathway. In column 11 last full paragraph, the present invention can be used as a prophylactic or a therapy for conditions such as coronary heart disease. See the claims.

Tabas (6,613,322) entitled "Method for Treating a Subject Suffering from Conditions Associated with an Extracellular Zinc Sphingomyelinase" teaches in column 8 last paragraph conditions treated include atherosclerotic vascular disease, coronary artery disease, and cerebral vascular disease. In column 9 first full paragraph, the inhibitor may be a peptide or polypeptide, a peptidomimetic compound, an organic compound, a nucleic acid, an inorganic compound or an antibody. The inhibitor inactivates zinc sphingomyelinase.

The claims differ from the above references in that they specify the compounds which inhibit the enzymes.

The specification teaches each of the claimed compounds is known to inhibit the respective enzymes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the claimed compounds to modulate the sphingosine pathway to treat vascular disease in view of the primary references because the specification teaches the claimed compounds are known to modulate the sphingosine pathway. The nexus between vascular disease and the sphingosine pathway is clearly described in the primary references above.

Further, some of the claimed compounds such as sodium fluoride, propranolol, and others are known to be administered to humans for various reasons and treating vascular disease would have been inherent in administering the same compounds for any reason.

The claims as newly amended further differ from the above references in that they recite the method treats acute myocardial ischemic events.

Friedrichs (US 2002/0150582) entitled "Method of Treating or Inhibiting Cellular Injury or Cell Death" teaches in paragraph 8, the sphingomyelinase pathway can be initiated by the release of TNF and is considered the predominant signaling pathway of the cytokine. This pathway has been demonstrated in cardiac myocytes. Claims 1 and 2 teach treating myocardial infarction or myocardial ischemia by providing a TNF antagonist.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the claimed compounds to treat acute myocardial ischemia because the primary references teach treating coronary artery disease in general which includes both chronic and acute disease and Friedrichs teaches specifically myocardial infarction by inhibiting the sphingomyelin pathway.

Applicant's arguments filed 9/21/07 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach treating acute myocardial ischemia as the claims have been amended to read.

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It is the examiner's position that Gamble teaches in column 11 last full paragraph, treating coronary heart disease. And Tabas teaches in column 8 last paragraph treating coronary artery disease. Treating coronary heart disease would encompass all types of coronary heart disease including acute myocardial ischemic events. And Friedrichs teaches inhibiting the sphingolipid pathway to treat myocardial ischemia.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 34 is it unclear if both or either (a) and (b) are included in the agent.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sabbandini (6,858,383) is a related patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ralph Gitomer  
Primary Examiner  
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